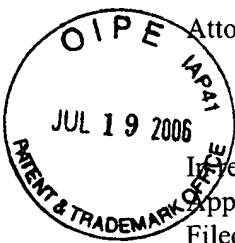


07-20-06

1634

PATENT

FTW



Attorney Docket No. 5470-401

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Stafford et al.

Application No.: 10/573,131

Filed: March 23, 2006

For: METHODS AND COMPOSITIONS FOR THE CORRELATION OF SINGLE NUCLEOTIDE POLYMORPHISMS IN THE VITAMIN K EPOXIDE REDUCTASE GENE AND WARFARIN DOSAGE

Confirmation No.: 4529

Group Art Unit: 1634

Examiner: TBD

Date: July 19, 2006

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. § 1.97(b)

Sir:

Attached is a list of documents on Form PTO-1449, together with a copy of any listed foreign patent document and/or non-patent literature. A copy of any listed U.S. patent and/or U.S. patent application publication is not provided herewith in accordance with the amendment by the U.S. Patent and Trademark Office to 37 C.F.R. § 1.98(a)(2)(ii) effective October 21, 2004.

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. § 1.97(b), within three months of the filing date of the above-referenced application or before the mailing of a first Office Action on the merits, whichever event occurs last. Therefore, no fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. § 1.56 and Section 609 of the MPEP.

Respectfully submitted,

*Mary L. Miller*

Mary L. Miller

Registration No. 39,303

Myers Bigel Sibley & Sajovec, P.A.  
P. O. Box 37428  
Raleigh, North Carolina 27627  
Telephone: (919) 854-1400  
Facsimile: (919) 854-1401  
Customer No. 20792

CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR § 1.10

Express Mail Label No.: EV 769236518 US

Date of Deposit: July 19, 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Evelyn B. Casey*  
Evelyn B. Casey

Substitute form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 2

**Complete if Known**

Application Number	10/573,131
Filing Date	March 23, 2006
First Named Inventor	Darrel W. Stafford
Group Art Unit	1634
Examiner Name	TBD
Attorney Docket Number	5470-401

**U.S. PATENTS AND PATENT PUBLICATIONS**

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	1.	US- 5,686,631		Li et al.	11/11/1997
	2.	US-2006/0084070 A1		Rieder et al.	04/20/2006
	3.	US-2006/0084081 A1		Rieder et al.	04/20/2006
	4.	US-2005/0271644 A1		Oldenburg	12/2005

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation
		Office	Number	Kind Code (if known)			
	5.	PCT	WO 2005/040367 A1		Baxter International	05/06/2005	

**OTHER NON PATENT DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	6.	Aquilante et al. "Influence of coagulation factor, vitamin K epoxide reductase complex subunit 1, and cytochrome P450 2C9 gene polymorphisms on warfarin dose requirements" <i>Clinical Pharmacology &amp; Therapeutics</i> 79(4):291-302 (2006)	
	7.	Bodin et al. "Cytochrome P450 2C9 (CYP2C9) and vitamin K epoxide reductase (VKORC1) genotypes as determinants of acenocoumarol sensitivity" <i>Blood</i> 106(1):135-140 (2005)	
	8.	D'Andrea et al. "A polymorphism in the VKORC1 gene is associated with an interindividual variability in the dose-anticoagulant effect of warfarin" <i>Blood</i> 106(1):645-649 (2005)	
	9.	Fregin et al. "Homozygosity mapping of a second gene locus for hereditary combined deficiency of vitamin K-dependent clotting factors to the centromeric region of chromosome 16" <i>Blood</i> 100(9):3229-3232 (2002)	
	10.	Gage et al. "Pharmacogenetics and Anticoagulant Therapy" <i>Journal of Thrombosis and Thrombolysis</i> 16(1/2):73-78 (2003)	
	11.	Gage et al. "PharmGKB Submission Update: VIII. PBAT Submission of Genetic Variation in VKORC1 to the PharmGKB Network" <i>Pharmacol Rev</i> 58(2):138-139 (2006)	
	12.	Geisen et al. "VKORC1 haplotypes and their impact on the inter-individual and inter-ethnic variability of oral anticoagulation" <i>Blood</i> 94(4):773-779 (2005)	
	13.	Harrington et al. "Pharmacodynamic resistance to warfarin associated with a Val66Met substitution in vitamin K epoxide reductase complex subunit 1" <i>Thromb Haemost</i> 93:23-26 (2005)	
	14.	International Search Report for PCT/US04/31481; date of mailing: March 28, 2005	
	15.	Kohn et al. "Natural selection mapping of the warfarin-resistance gene" <i>PNAS</i> 97(14):7911-7915 (2000)	
	16.	Kohn et al. "A gene-anchored map position of the rat warfarin-resistance locus, <i>Rw</i> , and its orthologs in mice and humans" <i>Blood</i> 96(5):1996-1998 (2000)	
	17.	Kohn et al. "Locus-Specific Genetic Differentiation at <i>Rw</i> Among Warfarin-Resistant Rat ( <i>Ratus norvegicus</i> ) Populations" <i>Genetics</i> 164:1055-1070 (2003)	
	18.	Lee et al. "Interethnic variability of warfarin maintenance requirement is explained by VKORC1 genotype in an Asian population" <i>Clinical Pharmacology &amp; Therapeutics</i> 79(3):197-205 (2006)	
	19.	Li et al. "Identification of the gene for vitamin K epoxide reductase" <i>Nature</i> 427:541-544 (2004)	
	20.	Li et al. "Polymorphisms in the VKORC1 gene are strongly associated with warfarin dosage requirements in patients receiving anticoagulation" <i>J. Med. Genet.</i> Online Publication April 12, 2006	
	21.	Loebstein et al. "Common genetic variants of microsomal epoxide hydrolase affect warfarin dose requirements beyond the effect of cytochrome P450 2C9" <i>Clinical Pharmacology &amp; Therapeutics</i> 77(5):365-372 (2005)	
	22.	Montes et al. "The c.-1639G>A polymorphism of the VKORC1 gene is a major determinant of the	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	10/573,131
		Filing Date	March 23, 2006
		First Named Inventor	Darrel W. Stafford
		Group Art Unit	1634
		Examiner Name	TBD
Sheet	2 of 2	Attorney Docket Number	5470-401

OTHER NON PATENT DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
		response to acenocoumarol in anticoagulated patients" <i>Br. J. Haematol.</i> <b>133</b> (2):183-187 (2006)	
	23.	Mushiroda et al. "Association of VKORC1 and CYP2C9 polymorphisms with warfarin dose requirements in Japanese patients" <i>J. Hum. Genet.</i> <b>51</b> (3):249-253 (2006)	
	24.	Pelz et al. "The Genetic Basis of Resistance to Anticoagulants in Rodents" <i>Genetics</i> <b>170</b> :1839-1847 (2005)	
	25.	Quteineh et al. "Vitamin K epoxide reductase (VKORC1) genetic polymorphism is associated to oral anticoagulant overdose" <i>Thromb. Haemost.</i> <b>94</b> (3):690-691 (2005)	
	26.	Reider et al. GenBank Accession No. AY 587020 "Homo sapiens vitamin K epoxide reductase complex, subunit 1 (VKORC1) gene, complete cds" May 14, 2004	
	27.	Reitsma et al. "A C1173T Dimorphism in the VKORC1 Gene Determines Coumarin Sensitivity and Bleeding Risk" <i>PloS Medicine</i> <b>2</b> (10):e312, published on-line October 11, 2005	
	28.	Rieder et al. "Effect of VKORC1 Haplotypes on Transcriptional Regulation and Warfarin Dose" <i>N Engl J Med</i> <b>352</b> (22):2285-2293 (2005)	
	29.	Rost et al. "Mutations in VKORC1 cause warfarin resistance and multiple coagulation factor deficiency type 2" <i>Nature</i> <b>427</b> :537-541 (2004)	
	30.	Sconce et al. "The impact of CYP2C9 and VKORC1 genetic polymorphism and patient characteristics upon warfarin dose requirements: proposal for a new dosing regimen" <i>Blood</i> <b>106</b> (7):2329-2333 (2005)	
	31.	Vecsler et al. "Combined genetic profiles of components and regulators of the vitamin K-dependent $\gamma$ - carboxylation system affect individual sensitivity to warfarin" <i>Thromb. Haemost.</i> <b>95</b> (2):205-211 (2006)	
	32.	Veenstra et al. "Association of Vitamin K epoxide reductase complex 1 (VKORC1) variants with warfarin dose in a Hong Kong Chinese patent population" <i>Pharmacogenetics and Genomics</i> <b>15</b> (10):687-691 (2005)	
	33.	Voora et al. "Use of Pharmacogenetics to Guide Warfarin Therapy" <i>Drugs of Today</i> <b>40</b> (3):247-257 (2004)	
	34.	Wadelius et al. "Common VKORC1 and GGCX polymorphisms associated with warfarin dose" <i>The Pharmacogenomics Journal</i> <b>5</b> (4):262-270 (2005)	
	35.	Wallin et al. "A molecular mechanism for genetic warfarin resistance in the rat" <i>The FASEB Journal</i> <b>15</b> :2542-2544 (2001)	
	36.	Wang et al. "VKORC1 Haplotypes Are Associated With Arterial Vascular Diseases (Stroke, Coronary Heart Disease, and Aortic Dissection)" <i>Circulation</i> <b>113</b> (12):1615-1621, published on-line March 20, 2006	
	37.	Yuan et al. "A novel functional VKORC1 promoter polymorphism is associated with inter-individual and inter-ethnic differences in warfarin sensitivity" <i>Human Molecular Genetics</i> <b>14</b> (13):1745-1751 (2005)	
	38.	Zhao et al. "Novel CYP2C9 genetic variants in Asian subjects and their influence on maintenance warfarin dose" <i>Clin Pharmacol Ther</i> <b>76</b> (3):210-219 (2004)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.